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Examination of Balance and Weightbearing in Post Anterior Cruciate Ligament Reconstruction Utilizing the Weight Bearing and Step Up/Over Tests on the Neurocom Balance Master

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EXAMINATION OF BALANCE AND WEIGHTBEARING IN POST ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION UTILIZING THE WEIGHT BEARING AND STEP UP/OVER TESTS ON THE NEUROCOM BALANCE MASTER

by

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This Scholarly Project, submitted by Kim Broadway, Carrie Grise, Nicky Yamamoto, and Franz Yuen in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

(Graduate School Advisor)

(Chairperson, Physical Therapy)

PERMISSION

Title	Examination of Balance and WeightBearing in Post Anterior Cruciate Ligament Reconstruction Utilizing the Weight Bearing and Step Up/Over Tests on the NeuroCom Balance Master
Department	Physical Therapy
Degree	Master of Physical Therapy

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Signature Kimberly Bradway

Signature Carrie Kerr

Signature

Signature

Date 12-19-03

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ABSTRACT

Currently in the United States, anterior cruciate ligament reconstruction (ACLR) has become one of the most commonly performed surgeries of the lower extremity. Although sports activities commonly cause injury to the ACL, non-athletic individuals are affected as well. With the increasing prevalence of the ACLR procedure, a need appears for researching the effects an ACLR has on balance and weight bearing.

The purpose of this study was to examine the effects an ACLR has on balance and weight bearing using the NeuroCom® Balance Master (NBM), version 8.02, Weight Bearing Squat (WBS) and Step Up/Over (SUO) tests with individuals who were at least 3 months post-op. Thirty-one participants (21 female and 10 males) between the ages of 18-53 (mean age = 24.74 years) with an ACLR took part in a one-time test session. Participants completed the Lysholm Knee Rating Scale functional assessment, a health questionnaire, and then had bilateral knee range of motion measured. The participants performed the WBS test at 0, 30, 60, and 90 degrees of knee flexion for a one second time interval at each position. They then performed 3 trials on each leg of the SUO test.

Test results for each participant were collected and data was entered into the SPSS Version 11.0 software system. Comparisons were made between data components using a one-sample t-test for the parametric test, a Mann-Whitney U test for the nonparametric test, and by qualitative analysis.

Due to significant differences found in this study, the overall results show that there are some knee deficits following an ACLR. Deficits were found in the involved leg versus the uninvolved leg and patellar grafts versus hamstring grafts in weight bearing, movement time, and impact index in the WBS and SUO tests. Lysholm Knee Rating Scale scores indicated good scores (87.73/100) for participants less than and equal to 18 months and excellent scores (91.00/100) for participants greater than 18 months post ACLR.

This study showed variable significant differences throughout test results due to several probable factors. Some limitations that may have hindered this study on balance and weight bearing were individual variability, age, vision, functional status, strength, proprioception, and the presence of other pathologies.

This study indicates that there is a need for further investigation to evaluate the effects an ACLR has on function. Recommendations such as a larger sample size, consistent testing times, shorter and variable time frames post-op, and utilizing multiple and repetitive tests may improve results. Hopefully, this will lead to better decision making on rehabilitation for ACLR's and improve the ability to solve increasingly complex problems resulting in efficient cost-effective care. Findings could possibly be used for guidelines on rehabilitation programs in patients with post ACLR's

CHAPTER I

INTRODUCTION AND LITERATURE REVIEW

The reconstruction of the anterior cruciate ligament (ACL) has dramatically increased over the past 20 years and has been widely studied. Approximately 95,000 ACL patients are seen each year with 50,000 of them requiring total reconstruction.[1] The common age group is in the high school and college-aged population because of the involvement in competitive sports.[2] The most common sports that have been associated with frequent ACL tears are football, soccer, volleyball, tennis, and basketball. Studies from the National Collegiate Athletic Association (NCAA) have shown that female athletes injure the ACL more frequently than their male counterparts.[3] This greater incidence of ACL injuries in women probably originates from several interrelated factors such as hamstring-quadriceps strength imbalances and joint laxity. Although these sports commonly cause injury to the ACL, non-athletic individuals are affected as well.

The ACL is one of four stabilizing ligaments in the knee, which include the posterior cruciate ligament and medial and lateral collateral ligaments.[4] It is the major stabilizing ligament of the knee. The ACL is a viseoelastic, avascular structure located in the center of the knee joint and runs upward and laterally from the anterior tibia and attaches to the lateral femoral condyle. This particular ligament prevents excessive anterior displacement and rotation of the lower leg with respect to the femur. A sudden deceleration or excessive twisting of the knee as well as hyperextension, hyperflexion or

lateral trauma to the knee frequently produces ACL impairments. Instability or a sensation that the knee is "giving out" may be a major complaint following this injury. The extent of the injury will determine if treatment will be conservative or operative.[5] If the ACL is not torn completely, conservative treatment may be prescribed with a strengthening, stretching and proprioceptive program to compensate for the impaired ACL. If there is a complete tear in the ACL, surgical reconstruction will be the choice of repair.

With the occurrence of a completely torn ACL, there are several techniques used to reconstruct the ACL. Since the ACL is unable to heal itself secondary to its avascularity, a similar structure must be inserted to replace it in the knee.[6] Several options from which surgeons may choose from include:

1. Autograft - an ACL derived from one's own body, such as patellar, hamstring or quadriceps graft
2. Allograft - an actual ACL transplanted from a cadaver
3. Synthetic graft – an artificially prepared ACL (i.e. carbon fibers).

Although all these procedures have their advantages and disadvantages the patellar graft is the most often used although the hamstring graft is gaining popularity. Synthetic types are still being studied and modified due to high failure rates.[7] A study by Miller and Gladstone[6] stated that hamstring tendon grafts have reduced harvest morbidity and improved soft tissue fixation techniques. Recent studies in the literature report found greater results with hamstring graft anterior cruciate ligament reconstruction (ACLR) with respect to functional outcome and patient satisfaction.[6] However, a study done by Bealle et al [7] states that failure and revision procedures still occur at approximately the

same frequency with either the patellar or hamstring graft. Therefore, ACLR procedures are still being judged and studied to determine which is the most successful.

Injury to the ACL, whether reconstructed, completely torn or partially torn, can significantly reduce the body's ability to balance effectively.[8] Balance, defined as the process in maintaining the center of gravity (COG) within the body's base of support, involves multiple neurogenic pathways.[9,10] The ability to maintain balance depends on afferent information the brain receives from proprioception, vision, vestibular, and musculoskeletal systems. Research indicates that after lower extremity joint trauma, a certain level of deafferentation occurs.[11-15] Reconstructive surgery can cause changes below the incision site which also disrupt proprioception. If proprioception is disrupted, an immediate effect on balance and function may arise. Therefore, the individual may become more reliant on their vision in the presence of a dysfunction of proprioception at the knee.

With an ACLR, muscle strength and range of motion (ROM) can be impaired which in turn effects musculoskeletal responses. These responses can include simple stretch reflexes, functional stretch reflexes, postural synergies, and complex equilibrium reactions.[12] Research shows that muscle strength will enhance dynamic stability while restriction in ROM will limit the individual's function and satisfaction.[16]

The goal of an ACLR is to improve function, quality of life, and reduce pain. Sundren et al [17] discovered that patients were satisfied with ACLR results 7 years after their reconstruction with 75 percent of the patients studied scoring an average of 84.8 out of a possible 100 (good to excellent) using the Lysholm Knee Rating Scale. However, Kowalk et al [9] discovered that in individuals 6-months post ACLR there was success in

restoring anterior and posterior knee stability, but there was a decrease in balance and weight bearing in the injured knee.

Squatting and stepping up and over movements are functionally relative to activities of daily living and important skills for independent lifestyles. Therefore, studying these movements is appropriate in assessing functional status of an individual with an impaired ACLR. Chmielwski et al [8] performed a study over a 6 week period assessing changes in squatting and step up and over movements in 10 individuals who were 1.5 to 6 weeks post ACLR. Results showed a significant decrease in weight bearing in the ACLR group on the involved side during 90° of bilateral squatting. With the step up and over movement, Chmielwski found that ACLR subjects had a slowed movement time on the involved side. Follow up weekly testing (weeks 2 to 6) showed significant increases in weight borne on the involved side and speed of step up and over time. The correlation of movement time and quadriceps strength (involved leg) suggests that quadriceps weakness results in slowing of step negotiation and an increase in weight bearing on the uninvolved leg during squat.

Purpose

The purpose of this study was to determine the effects an ACLR has on balance and weight bearing using the NeuroCom BalanceMaster (NBM) Weight Bearing Squat (WBS) and Step Up/Over (SUO) tests and Lysholm Knee Rating Scale. This study is warranted due to the small amount of literature discussing the impact the ACL has on proprioception and balance on functional activities. The research questions that will be addressed are:

1. Is there a significant difference in test results of the involved leg versus the uninvolved leg in all participants in the WBS and SUO tests following an ACLR?
2. Is there a significant difference in test results of the involved leg in participants less than or equal to 18 months versus participants greater than 18 months post-op in the WBS and SUO tests following an ACLR?
3. Is there a significant difference in movement time in the SUO test between participants with an ACLR and normative data found in the NBM Operator's Manual?
4. Is there a significant difference in test results of the involved leg in participants with patellar versus hamstring grafts in the WBS and SUO tests following an ACLR?
5. Is there a significant difference in test results of the involved leg versus the uninvolved leg in participants with a hamstring graft in the WBS and SUO tests following an ACLR?
6. Is there a significant difference in test results of the involved leg versus the uninvolved leg in participants with a patellar graft in the WBS and SUO tests following an ACLR?

The first hypothesis is that there will be a significant difference in test results of the involved leg versus the uninvolved leg in all participants with the WBS and SUO tests. The null hypothesis is that there will be no significant difference of the involved leg versus the uninvolved leg in all participants with the WBS and SUO tests.

The second hypothesis is that there will be a significant difference in test results between the involved leg compared with the uninvolved leg with WBS and SUO in participants less than or equal to 18 months versus greater than 18 months post-op. The null hypothesis is that there will be no significant difference in WBS and SUO between the involved leg and uninvolved leg in both groups.

The third hypothesis is that there will be a significant difference in movement time in patients with ACLR compared to normative data with the SUO test. The null hypothesis is that there will be no significant difference in movement time with the SUO test between patients with and ACLR and normative data.

The fourth hypothesis is that there will be a significant difference in test results of the involved leg in participants with patellar versus hamstring grafts in the WBS and SUO tests. The null hypothesis is that there will be no significant difference of the involved leg in participants with patellar versus hamstring grafts in the WBS and SUO tests.

The fifth hypothesis is that there will be a significant difference in test results of the involved leg versus the uninvolved leg in participants with a hamstring graft in the WBS and SUO tests. The null hypothesis is that there will be no significant difference of the involved leg versus the uninvolved leg with a hamstring graft in the WBS and SUO tests.

The final hypothesis is that there will be a significant difference in test results of the involved leg versus the uninvolved leg in participants with a patellar graft in the WBS and SUO tests. The null hypothesis is that there will be no significant difference of the involved leg versus the uninvolved leg with a patellar graft in the WBS and SUO tests.

Clinical Significance

Research in anatomy, biomechanics, epidemiology, graft sources, fixation methods, physical therapy rehabilitation and clinical outcomes of the ACLR has rendered the anterior cruciate ligament to become better understood in terms of function and it's ability to consistently and predictably be reconstructed. ACL injuries, once considered career ending injuries, are more often a minor obstacle in an athlete's or nonathletic person's career path. All these studies have improved the knowledge and understanding for improvements in surgical, rehabilitation, and prophylactic techniques.

Optimistically, this study will lead to better decision making on rehabilitation for ACLR's and improve the ability to solve increasingly complex problems resulting in efficient cost-effective care. Findings could possibly be used for guidelines on rehabilitation in patients with post ACLR's.

CHAPTER II

METHODOLOGY

Prior to the start of this study, final approval was obtained from the University of North Dakota (UND) Institutional Review Board for the use of human subjects. A copy of the Human Subjects Review Form and the approval letter from UND is located in Appendix A. All participants interested in participating were informed that their involvement was strictly voluntary. They were provided a detailed explanation of the components in this study. Each participant was provided a written consent form, which was signed prior to participating. A copy of the consent form is located in Appendix B. Participants were also asked to complete a Lysholm Knee Rating Scale functional assessment and a brief health questionnaire to identify possible safety or health concerns. Copies of the functional assessment and health questionnaire are located in Appendix C.

Confidentiality of the participants' information and results of the study was maintained by assigning random numbers to represent the data. The research data and the consent forms from this study will be stored separately in locked cabinets in the Physical Therapy Department at UND. This information will only be available to the researchers conducting this study. The data will be kept for 3 years after the study and then will be discarded appropriately.

Participants

Participants were recruited using word of mouth from the researchers and posting of fliers around campus. Inclusion criteria for assessment of each participant required him/her to have undergone an ACLR at least 3 months prior to this study and were at least 18 years of age. Exclusion criteria for each participant were as follow: posterior cruciate ligament involvement; current back, hip, knee, or ankle pathologies; neurological or vestibular disorders; use of medications that may affect balance (i.e. pain killers, hypertensive agents, etc.); and use of any assistive device (crutches or braces). Thirty-one participants, 21 females and 10 males, ages 18 to 53 (mean age = 24.74 years) who met the inclusion/exclusion criteria were asked to participate in the study. Three of these participants had bilateral ACLR's, the remaining 28 participants had unilateral ACLR's. All participants met the criteria and were involved in the study. Participants were tested in a one-time session lasting 20-30 minutes.

Instrumentation Questionnaires

The Lysholm Knee Rating Scale is a self-administered questionnaire that takes approximately 5 minutes to complete.[18] The questionnaire is used to measure the level of function in people with knee ligament injuries. It consists of 8 sections that cover all areas of knee function. The Lysholm Knee Rating Scale is a valid and reliable survey that is used frequently in the health care profession.

An additional questionnaire created by the researchers was used to cover information not included in the Lysholm Knee Rating Scale. Information was needed in order to properly obtain all of the inclusion/exclusion criteria for assessment and data analysis. Questions in this survey were related to past medical history and injuries,

current medications, psychological conditions, vision problems, date/type of surgery, history of falls, age of participants, type of physical therapy, and current level of activity.

Goniometry

The goniometer is an apparatus used to measure the joint angles created by the bones of the human body using the proximal and distal bones of the joint being evaluated.[19] The recommended position for testing of the knee range of motion is supine and goniometer alignment is measured as follows: center of goniometer fulcrum over the femur on the lateral epicondyle; using the greater trochanter, align the proximal arm along the lateral midline of the femur; and using the lateral malleolus and fibularhead, align the distal arm along the lateral midline of the fibula. Using a universal goniometer, measurement of joint range and joint position has been shown to have a good to excellent reliability and validity.

NeuroCom Balance Master

The NeuroCom Balance Master (NBM) version 8.02 (NeuroCom International Inc., 9570 SE Lawnfield Road, Clackamas, Ore 97015-9611) is a computer software program that is commonly used in physical therapy to assess balance. The system operates on two forceplates (9" x 60") resting on 4-load cells on which the participant stands to determine the amount of force exerted by each foot.[20] The total force information is transferred on the computer system where calculations are performed. The computer screen is equipped with a cursor to provide visual feedback about the location of the participants' center of gravity. The computerized measurements and feedback systems are what make the system unique and beneficial to both the participant and the

researcher. In general the NBM demonstrates good to excellent reliability. Pictures of the NBM are located in Appendix D.

Hamman et al [21] determined that a high learning curve exists when using the NBM. They also found that this was primarily present during the first few training sessions but eventually reached a plateau. This demonstrates the need to provide each participant with a training session prior to the actual collection of data.

The NBM has a wide variety of standardized balance assessments and training programs. Two of the balance assessments used in this study included the WBS and SUO. The WBS component according to the NBM Operator's Manual has a high reliability for normal adults. The SUO component according to the NBM Operator's Manual has moderate to high reliability for normal adults. Both components have sensitivity to ACL injuries. The WBS measures the amount of weight borne on each leg during a one second time frame while the participant is standing with knees at 0 degrees of knee flexion, at 30 degrees of knee flexion, at 60 degrees of knee flexion, and at 90 degrees of knee flexion.[20] Normal individuals maintain body weight within 7% of equal on the two legs over full range of squatting positions.[22] Two components of balance are measured including: COG and percent body weight. An example of the WBS analysis is located in Appendix E. The definitions, as per the NBM Operator's Manual, are as follows:[20]

1. COG – an imaginary point in which the total mass of the body may be considered to be concentrated with respect to the pull of gravity. In normal individuals standing quietly erect, the COG is located at the level of S1-S2 and located very slightly in front of the ankle joints.

2. Percent Body Weight – the ratio of the amount of weight on one side (left or right) to the patients total body weight. Good scores are those where the left and right legs are each bearing very close to 50% of body weight; the greater the discrepancy (asymmetry), the worse the score.

The SUO measures left/right leg differences, vertical force control, limb loading, limb unloading, and execution time while the participant steps up onto an eight inch curb with one foot, lifts the other foot over the curb and down onto the floor, and steps down with the curb foot. Each participant is given three trials on each leg and an average of these trials is used for the data. Three components of balance were measured including: lift-up index, movement time, and impact index. An example of the SUO analysis is located in Appendix F. The definitions, as per the NBM Operator's Manual, are as follows:[20]

1. Lift-Up Index – the average maximum force exerted by the step-up leg, expressed as a percent of body weight. Close to equal performances on each leg are expected and are good.
2. Movement Time – the average amount of time to complete the step over is expressed in seconds. Scoring begins with the initial COG shift to the non-stepping leg, and ends with the impact of that leg onto the surface. The faster the time, the better the scores.
3. Impact Index – the average maximum force transmitted through the lagging leg as it lands on the surface, expressed as a percent of body weight. The step-up leg must switch from concentric control (lift the body) to eccentric control (lower the body) as the COG moves in front of the body while moving

over the step. The amount of impact force transmitted through the step down leg as it lands is an indication of eccentric control in the step-up leg. Low impact forces reflect appropriate eccentric control and are good, while high impact forces reflect diminished eccentric control and are worse.

Pilot Study

After the researchers had instruction in and practice on the NBM, a pilot study was performed in order to establish intrarater (test-retest) reliability for the rater. Ten participants ranging in age from 24-55 were assessed using the WBS and SUO tests in the same manner as described in the assessment procedures. The instructions in the NBM Operator's Manual were followed during the assessment of the participants. In order to establish intrarater reliability, each participant completed both tests two times, approximately one week apart. The SPSS Version 11.0 (SPSS, Inc., Chicago, IL) was used to calculate intrarater reliability.

Intrarater Reliability

An intraclass correlation coefficient (ICC) was calculated from a repeated measures analysis of variance (ANOVA) in order to assess test-retest reliability, testing the participant on different days. The ICC formula was used, as suggested for intrarater reliability. Intrarater reliability results are reported in Table 1.

ICC Interpretation

There are no standard values set for acceptable reliability when calculating the ICC. Values range between 0.00 and 1.00, with numbers falling closer to 1.00 representing stronger reliability scores. Reliability values were compared to the set values in the NBM Operator's Manual. Using the ICC interpretation listed in Table 2,

values obtained for intrarater reliability show moderate to high reliability, except on the WBS 60 degrees where reliability showed to be poor.

Table 1. SUO and WBS Intrarater Reliability Using ICC

Variable	Rater
SUO, Lift Up Index on left	.8873
SUO, Lift Up Index on right	.6311
SUO, Movement Time on left	.7384
SUO, Movement Time on right	.8415
SUO, Impact Index on left	.7975
WBS 0 degrees on left	.6515
WBS 0 degrees on right	.6515
WBS 30 degrees on left	.8213
WBS 30 degrees on right	.8213
WBS 60 degrees on left	.5208
WBS 60 degrees on right	.5208
WBS 90 degrees on left	.7444
WBS 90 degrees on right	.6785

Table 2. ICC Interpretation

ICC Value	Interpretation
> 0.80	High
0.60-0.80	Moderate
< 0.60	Poor

Assessment Procedure

Participant testing took place in the Physical Therapy Department at UND. This study began with the participants filling out the Lysholm Knee Rating Scale and being interviewed with a short questionnaire. Following the questionnaire, researchers used a goniometer to assess the participants range of motion of both knees. The range of motion was measured one time with the participant in the recommended supine position first with the heel slid back towards the buttocks as far as possible; then with the heel resting on a towel roll in full extension. Participants were then taken to the NBM for final

testing and asked to remove their socks and shoes, and instructions were given on how to perform the WBS and SUO tests. Participants were then positioned on the forceplate according to the directions given by the NBM for the WBS to assess the one second time frame in 0 degrees of knee flexion, 30 degrees of knee flexion, 60 degrees of knee flexion, and finally 90 degrees of knee flexion. A fixed goniometer was used to ensure the correct degree of knee flexion. Participants then performed 3 trials on each leg of the SUO test on an eight inch curb. At the same time the second researcher was spotting. Brief rest breaks were given between each test. Following testing, results were discussed with each participant.

Data Analysis

For each participant the data collected included the Lysholm Knee Rating Scale, questionnaire, goniometry measurements, WBS, and SUO. Data were entered into the SPSS Version 11.00 software system. Comparisons were made between the data components using an independent samples t-test for the parametric test, a Mann-Whitney U test for the nonparametric test, and by qualitative analysis.

Reporting of Results

Upon completion of this study, a copy of the results of this scholarly project was given to the University of North Dakota Department of Physical Therapy and the Harley E. French Library of the Health Sciences. This study was completed to fulfill the requirements of the University of North Dakota School of Medicine and Health Sciences Physical Therapy Program.

CHAPTER III

RESULTS

The results consisted of WBS and SUO scores from the NBM, version 8.02. Comparisons were made between test results, health questionnaire, Lysholm Knee Rating Scale, and goniometric data. Statistical tests were run using the data above to determine if any significant differences existed.

Participant Profile

Thirty-one participants, 21 females and 10 males, ages 18-53 (mean age = 24.74 years), took part in this study. Three of the 31 participants had bilateral ACLR's with the mean being 9.67 years since their first ACLR. For the purpose of this study the most recent surgery date was used as the involved leg. All other participants had unilateral ACLR's. All participants were included in this study and no data were discarded. This study consisted of a one time testing session on the NBM, in conjunction with goniometry, Lysholm Knee Rating Scale, and a health questionnaire.

Descriptive Statistics

Descriptive statistics including mean, standard deviation, skewness, and kurtosis were calculated from the data gathered during the assessment. For a listing of values, see Table 3. The skewness and kurtosis values were used to determine if the data collected were normally distributed.

Table 3. Descriptive Statistics for the SUO and WBS Tests

Variable	N	Mean	Median	SD
Age in years	31	24.74	22.00	9.34
Time post op in months	31	43.65	36.00	49.82
SUO, Lift-up index (in %)	62	37.16	36.00	7.74
SUO, Lift-up index, left (in %)	31	36.84	36.00	7.90
SUO, Lift-up index, right (in %)	31	37.48	36.00	7.68
SUO, Movement time (in sec)	62	1.40	1.33	.23
SUO, Movement time, left (in sec)	31	1.39	1.33	.25
SUO, Movement time, right (in sec)	31	1.41	1.33	.21
SUO, Impact index (in %)	62	31.85	31.00	10.90
SUO, Impact index, left (in %)	31	33.84	32.00	11.67
SUO, Impact index, right (in %)	31	29.87	28.00	9.86
WBS, 0 degrees (in %)	62	50.00	50.00	3.65
WBS, 0 degrees, left (in %)	31	48.81	48.00	3.48
WBS, 0 degrees, right (in %)	31	51.19	52.00	3.48
WBS, 30 degrees (in %)	62	50.00	50.00	4.03
WBS, 30 degrees, left (in %)	31	48.55	49.00	3.78
WBS, 30 degrees, right (in %)	31	51.45	51.00	3.78
WBS, 60 degrees (in %)	62	50.00	50.00	5.35
WBS, 60 degrees, left (in %)	31	48.39	49.00	5.14
WBS, 60 degrees, right (in %)	31	51.61	51.00	5.14
WBS, 90 degrees (in %)	62	50.00	50.00	4.73
WBS, 90 degrees, left (in %)	31	48.58	49.00	4.54
WBS, 90 degrees, right (in %)	31	51.42	51.00	4.54

Research Questions

The variables that were analyzed for the SUO were the lift-up index shown in percent body weight, movement time shown in seconds, and impact index shown as a percent body weight. The variable that was analyzed for the WBS was the amount of weight borne on each leg, shown as a percent, at 0 degrees of knee flexion, 30 degrees of knee flexion, 60 degrees of knee flexion, and 90 degrees of knee flexion. Variables were analyzed on both the involved and uninvolved leg. To determine if there were significant differences in test results, analytical statistics were completed using a Mann-Whitney U

test due to the presence of skewed and kurtosed data and a one-sample t-test. An alpha level of .05 was used to determine if there was a significant difference with the following:

1. The involved leg versus the uninvolved leg in all participants in the WBS and SUO following an ACLR. There was a significant difference (p=.004) in the WBS 60 degrees with the involved leg having a mean of 48.06% and the uninvolved leg having a mean of 51.94%. A significant difference (p=.040) was found in the WBS 90 degrees with the involved leg having a mean of 48.52% and the uninvolved leg having a mean of 51.48%. The results are listed in Table 4.

Table 4. Results for a Mann-Whitney U. Involved Leg Versus Uninvolved Leg in All Participants

Variable	Leg	N	Mean	Median	Z	p
SUO, Lift-up index (%)	Involved	31	38.29	36.00	-.98	.327
	Uninvolved	31	36.03	35.00		
SUO, Movement time (sec)	Involved	31	1.38	1.33	-.40	.688
	Uninvolved	31	1.42	1.33		
SUO, Impact index (%)	Involved	31	33.10	29.00	-.04	.967
	Uninvolved	31	30.61	31.00		
WBS, 0 degrees (%)	Involved	31	49.58	50.00	-.87	.384
	Uninvolved	31	50.42	50.00		
WBS, 30 degrees (%)	Involved	31	49.52	50.00	-.996	.319
	Uninvolved	31	50.48	50.00		
WBS, 60 degrees (%)	Involved	31	48.06	48.00	-2.91	.004*
	Uninvolved	31	51.94	52.00		
WBS, 90 degrees (%)	Involved	31	48.52	49.00	-2.06	.040*
	Uninvolved	31	51.48	51.00		

*$p \leq .05$

2. The test results of the involved leg in participants less than or equal to 18 months versus participants greater than 18 months post-op in the WBS and SUO tests following an ACLR. No significant differences were found. The results are listed in Table 5.

Table 5. Results for a Mann-Whitney U. Involved Leg in Participants Less Than or Equal to 18 Months Versus Participants Greater Than 18 Months Post-Op

Variable	Time Post-op	N	Mean	Median	Z	p
SUO, Lift-up index (%)	≤ 18 months	15	39.73	41.00	-.77	.440
	> 18 months	16	36.94	36.00		
SUO, Movement time (sec)	≤ 18 months	15	1.43	1.50	-1.29	.199
	> 18 months	16	1.33	1.33		
SUO, Impact index (%)	≤ 18 months	15	32.33	28.00	-.38	.707
	> 18 months	16	33.81	35.50		
WBS, 0 degrees (%)	≤ 18 months	15	50.20	50.00	-.72	.474
	> 18 months	16	49.00	49.00		
WBS, 30 degrees (%)	≤ 18 months	15	49.53	51.00	.00	1.00
	> 18 months	16	49.50	50.00		
WBS, 60 degrees (%)	≤ 18 months	15	47.40	47.00	-.58	.565
	> 18 months	16	48.69	48.50		
WBS, 90 degrees (%)	≤ 18 months	15	47.40	47.00	-1.29	.197
	> 18 months	16	49.56	50.00		

*p≤.05

3. The movement time in the SUO test between participants with an ACLR and normative data found in the NBM Operator's Manual. The variables looked at were age and the type of graft used for reconstruction. There was a significant difference (p=.010) in participants less than 40 years of age with patellar grafts with a mean of 1.54 seconds compared to the normative data mean of 1.2 seconds. A significant difference (p=.002) was found in participants greater than 40 years of age with patellar grafts with a mean of 1.41 seconds compared to the normative data mean of 1.3 seconds. The results are listed in Table 6. No comparisons were made between participants with a hamstring graft greater than 40 years of age to normal data due to the lack of participants that fit into this category. Also, only the variable movement time could be compared to normal data due to the lack of information obtained from the data. Participants body weight was needed to

compare the variable lift-up index and impact index to normal data and this was not included in the data collection.

Table 6. Results for a One-Sample T-Test. Movement Time of Participants Less Than 40 Years of Age and Greater Than 40 Years of Age With a Patellar Versus Hamstring Grafts Compared to Normative Data

Variable	N	Mean	SD	t	p
SUO, Movement time, >40 years of age with patellar grafts (sec)	3	1.54	.042	10.12	.010*
SUO, Movement time, < 40 years of age with patellar grafts (sec)	16	1.41	.228	3.68	.002*
SUO, Movement time <40 years of age with hamstring grafts (sec)	10	1.24	.143	.906	.389

*$p \leq .05$

4. The test results of the involved leg in participants with patellar versus hamstring grafts in the WBS and SUO tests following an ACLR. There is a significant difference (p=.017) in the SUO movement time with the hamstring grafts having a mean of 1.24 seconds and the patellar grafts having a mean of 1.43 seconds. A significant difference (p=.031) was found in the SUO impact index with the hamstring grafts having a mean of 41.00% and the patellar grafts having a mean of 30.68%. The results are listed in Table 7.
5. The test results of the involved leg versus the uninvolved leg in participants with a hamstring graft in the WBS and SUO tests following an ACLR. There was a significant difference (p=.008) in the WBS 30 degrees with the involved leg having a mean of 51.60% and the uninvolved leg having a mean of 48.40%. The results are listed in Table 8.
6. The test results of the involved leg versus the uninvolved leg in participants with a patellar graft in the WBS and SUO tests following an ACLR. There

Table 7. Results for a Mann-Whitney U. Involved Leg in Participants With a Patellar Versus Hamstring Graft

Variable	Type of graft	N	Mean	Median	Z	p
SUO, Lift-up index (%)	Hamstring	10	42.10	42.50	-1.61	.108
	Patellar	19	36.74	35.00		
SUO, Movement time (sec)	Hamstring	10	1.24	1.21	-2.39	.017*
	Patellar	19	1.43	1.39		
SUO Impact index (%)	Hamstring	10	41.00	42.00	-2.16	.031*
	Patellar	19	30.68	28.00		
WBS, 0 degrees (%)	Hamstring	10	51.00	51.00	-1.52	.128
	Patellar	19	48.89	48.00		
WBS, 30 degrees (%)	Hamstring	10	51.60	51.00	-1.87	.061
	Patellar	19	48.89	48.00		
WBS, 60 degrees (%)	Hamstring	10	50.00	50.00	-1.40	.160
	Patellar	19	47.11	47.00		
WBS, 90 degrees (%)	Hamstring	10	48.80	50.00	-.39	.695
	Patellar	19	48.42	49.00		

*p≤.05

Table 8. Results for a Mann-Whitney U. Involved Versus Uninvolved Leg in Participants With Hamstring Graft

Variable	Leg	N	Mean	Median	Z	p
SUO, Lift-up index (%)	Involved	10	42.10	42.50	-.87	.383
	Uninvolved	10	39.00	37.50		
SUO, Movement time (sec)	Involved	10	1.24	1.21	-.87	.383
	Uninvolved	10	1.34	1.28		
SUO, Impact index (%)	Involved	10	41.00	42.00	-1.10	.272
	Uninvolved	10	35.10	37.50		
WBS, 0 degrees (%)	Involved	10	51.00	51.00	-1.25	.210
	Uninvolved	10	49.00	49.00		
WBS, 30 degrees (%)	Involved	10	51.60	51.00	-2.67	.008*
	Uninvolved	10	48.40	49.00		
WBS, 60 degrees (%)	Involved	10	50.00	50.00	-.30	.761
	Uninvolved	10	50.00	50.00		
WBS, 90 degrees (%)	Involved	10	48.80	50.00	-1.14	.254
	Uninvolved	10	51.20	50.00		

*p≤.05

was a significant difference (p=.048) in the WBS 0 and 30 degrees with the involved leg having a mean of 48.89% and the uninvolved leg having a mean of 51.11%. A significant difference (p=.001) was found in the WBS 60 degrees with the involved leg having a mean of 47.11% and the uninvolved leg having a mean of 52.89%. The results are listed in Table 9.

Table 9. Results for a Mann-Whitney U. Involved Versus Uninvolved Leg in Participants With Patellar Grafts

Variable	Leg	N	Mean	Median	Z	p
SUO, Lift-up index (%)	Involved	19	36.74	35.00	-.57	.568
	Uninvolved	19	34.68	35.00		
SUO, Movement time (sec)	Involved	19	1.43	1.39	-.25	.804
	Uninvolved	19	1.46	1.42		
SUO, Impact index (%)	Involved	19	30.68	28.00	-.44	.661
	Uninvolved	19	29.05	31.00		
WBS, 0 degrees (%)	Involved	19	48.89	48.00	-1.98	.048*
	Uninvolved	19	51.11	52.00		
WBS, 30 degrees (%)	Involved	19	48.89	48.00	-1.98	.048*
	Uninvolved	19	51.11	52.00		
WBS, 60 degrees (%)	Involved	19	47.11	47.00	-3.30	.001*
	Uninvolved	19	52.89	53.00		
WBS, 90 degrees (%)	Involved	19	48.42	49.00	-1.67	.096
	Uninvolved	19	51.58	51.00		

*$p \leq .05$

Lysholm Knee Rating Scale

Another item that was addressed was the Lysholm Knee Rating Scale. The average score found for participants less than or equal to 18 months was 87.73 out of 100 which indicates a good score (scores ranged from 69 to 100). The average score for participants greater than 18 months post-op was 91.00 out of 100 which indicates an excellent score (scores ranged from 69 to 100). These scores were compared to the Lysholm Knee Rating Scale whose interpretation is shown in Table 10.[18]

Table 10. Lysholm Interpretation of Total Scores

Excellent	>90 points	No problems
Good	84 to 90 points	Minor limitations
Fair	65 to 83 points	Problems during sports
Poor	<65 points	Instability in sports and with almost all ADLs

After comparing the variables that the participants reported as problems and how many actually had abnormal test results using qualitative analysis, there was no correlation between the two variables. Some participants listed problems, but had normal test results while other participants listed no problems yet had abnormal test results. A summary of participant reported problems according the Lysholm Knee Rating Scale are listed in Table 11.

Table 11. Results of the Lysholm Knee Rating Scale (n = 31)

Variable	**Number of Participants Reporting Problems**
Limp	6
Support (cane/crutch)	0
Locking	7
Instability	18
Pain	14
Swelling	8
Stairs	4
Squatting	7

Twenty-four out of the 31 participants reported that they experienced problems; however, only 4 participants that listed problems had abnormal test results. There was no conclusive data suggesting that multiple problems listed by participants always led to abnormal tests results. This study showed that the majority of the participants that had abnormal results complained of instability, pain with light activities, and swelling. When looking at the problematic activities that were part of the WBS and SUO tests, it was

found that these reported problems did not correlate to abnormal test results. Of the 4 participants that listed problems with stairs, part of the SUO test, none had abnormal test results. Of the 7 participants that listed problems with squatting, part of the WBS test only one had abnormal test results.

CHAPTER IV

DISCUSSION AND CONCLUSION

The results of this study show that there are several significant findings related to the ACLR research questions presented. Interpretations and comparisons were made using previous published research and the data collected in this study. Interpretations are discussed below addressing the research questions.

In the comparison of the WBS and SUO tests for the involved versus the uninvolved leg in all participants, the data showed some significant differences. In the WBS test there was significantly less weight bearing on the involved leg at 60 (3.96%) and 90 degrees (3.88%). This is consistent with studies that show as a normal individual increases knee flexion, greater stress is placed on the ACL which alters function.[23,24] Chimielewski[8] found that there was significantly less weight bearing on the involved leg during squatting movements at 90 degrees and significant differences in slowed movement time for patients with an ACLR. They were tested one week post-op with weekly follow up tests until 6 weeks. These significant results may be attributed to the length of time since the participants had their ACLR. Studies have shown it may take athlete's 3 months to recover and return to sport whereas non athlete's may take up to 9 months to fully recover from an ACLR.[25,26] There were no significance differences in the involved leg in participants less than or equal to 18 months versus participants greater than 18 months post-op in the SUO and WBS tests. This may be due to the fact that the participants in this study ranged from 3 months to 18 years post-op.

In addressing the research question dealing with involved versus the uninvolved leg there were minimal significant differences. Therefore, hamstring and patellar grafts were then compared. The hamstring graft consistently out performed the patellar graft in the WBS and SUO tests. The patellar graft showed a significant decrease in weight bearing on the involved leg compared to the uninvolved leg at 0 degrees (2.22%), 30 degrees (2.22%), and 60 degrees (5.78%) of knee flexion. In the same tests, the hamstring graft showed a significant decrease on the involved leg compared to the uninvolved leg in the WBS at 30 degrees (2.00%). When the grafts were compared to each other using the involved leg, the patellar graft was significantly slower than the hamstring graft in the SUO movement time (1.43 sec vs.1.24 sec) and had a decreased impact index (41.00% and 51.00%). These findings are consistent with a study by Rudroff,[27] which states that a decrease in function of the patellar graft performance may be due to altered activation of the quadriceps and hamstring muscles. This may be a reason why the participants' with patellar grafts had more significant differences with the WBS test compared to the hamstring graft participants. Research reports seem to favor the hamstring graft as the best choice to increase the return of function.[6,16,27]

This study's participant profile was consistent with research that shows that females have a greater incidence of ACL injury. This study had 21 females and 10 males which is a good representation of the population with ACLR. When looking at the data obtained from the health questionnaire, no data were used to determine if there were any factors that correlated with abnormal results on the WBS and SUO tests. The health questionnaire was only used to determine that all participants were safe and healthy.

Although this study produced some significant data, it was not consistently significant. This may be due to the fact that the majority of participants in this study averaged 9.67 years post-op ACLR. The long period of time allowed the participants to fully recover in ROM and strength which seems to play a factor in function. All participants in this study had no deficits in ROM and the majority of the participants' Lysholm Knee Rating Scale scores ranged form good to excellent. A reduction in the post-op time frame may produce more significant data.

The results of the Lysholm Knee Rating Scale showed on all participants that 22.58% had a fair score, 29.03% had a good score, and 48.39% had an excellent score (Table 10). Of the 22.58% that had a fair score, 85.71% were $\leq$ 18 months post-op. Of the 29.03% that had a good score, 33.33% were $\leq$ 18 months post-op. Of the 48.39% that had an excellent score, 40% were $\leq$ 18 months post-op. This shows that the shorter the recovery time the participant has the more problems they will report and their total score will be lower. As the recovery time lengthens, the participants' report less problems and their total scores increase. Sundgren et al[17] found that 75% of the participants with an ACLR had good to excellent scores after 5-7 years. This is consistent with a study by Ruiz et al[28] that showed that improved scores are sustained beyond 7 years.

Although the majority of participants had Lysholm Knee Rating Scale scores good to excellent, there were still complaints of instability and pain. A few of the participants reported problems with stairs (4/31) and squatting (7/31) while approximately half of the participants reported problems with pain (14/31) and instability (18/31). The reported problems of pain and instability can lead to problems with stairs and squatting. A probable reason why these participants reported problems in these areas

but had normal WBS and SUO test results could be due to the fact that with these tests the participants were only asked to step over one step 3 times and squat once for a one second time frame. Normal everyday functioning like these activities is more likely to cause problems because they are often done repetitively and for longer time frames. For example, a normal flight of stairs is approximately 8 stairs and with basketball an athlete has to remain in a squatting position for a greater amount of time.

Limitations

There are many factors that may hinder balance, some examples include: individual variability, age, vision, functional status, strength, proprioception, and other pathologies. This study did try to eliminate as many of these factors as possible by using exclusion criteria. Although this study primarily focused on ROM, weight bearing status, and components of dynamic and static balance, it is impossible to totally eliminate extraneous factors.

Limitations that may have affected this study's data collection include: variations in time of day in which participants were tested, bilateral participant inclusion and sample size, only one testing session, time frame of testing, lack of normative data for subjects under 20 years of age, and only 2 brief functional tests were used to assess participants.

Participants in this study were tested at various hours throughout the day. The difference in testing times may have affected the performance of the participant due to prior daily activities and fatigue levels. The time constraint of the researchers and participants may have had an impact on the results.

Three of the 31 participants had bilateral ACL reconstructions; this may have impacted WBS and SUO test results when comparing involved leg to uninvolved leg.

For these 3 instances, the researchers felt the participants were far enough post-op (mean = 9.76 years) with their first ACLR to be included in this study. The involved leg was referred to the knee that was most recently reconstructed. These 3 participant results were taken out of the data and the Mann-Whitney-U test was redone. The results that differed were the SUO movement time and impact index in the involved leg in participants with a patellar versus hamstring graft and the WBS at 0 and 30 degrees in the involved leg in participants with a patellar graft. These results were significant with the 3 participants included and were reduced to just below p= 0.05 which were not significant when these 3 were taken out. Sample size may add to the significance with a larger number and variety of participants.

The NeuroCom Balance Master has no normative data for subjects under the age of 20. This indicated that a comparison could only be made between data collected and normative data with the 20 to 40 year old participants. In this study there were 10 participants that were under the age of 20.

The participants were only asked to perform two brief functional tests and these tests were only components of functional activities that they would perform in every day life. They were not performed enough in the testing session to bring on the pain and instability that may cause problems in performance of these tests; therefore many of the participants reported problems on the Lysholm Knee Rating Scale, but displayed normal test results.

Recommendations

A few recommendations can be made in regards to this study. The recommendations below address the limitations along with other factors that could

improve the results of future studies. It is suggested that the following recommendations be considered.

A suggestion for future studies would be to increase the number of participants involved in the study and add more exclusion criteria. Having a larger sample size would decrease the homogeneity of subjects. It would also allow for greater and equal amount of hamstring and patellar grafts which has the potential of increasing reliability of test results. By adding more exclusion criteria the bilateral ACLR participants would be eliminated thus increasing the accuracy of results.

Although this study tested participants at various hours throughout the day, no remarkable discrepancies in performance were noted. It would be recommended that participants be tested within a certain time interval to decrease possible factors such as fatigue level and prior daily activities that may hinder balance performance.

A more concrete recovery time frame would be suggested for future studies. In this study, the time frame from ACLR ranged from as early as 3 months to as late as 18 years. Having a shorter time frame may provide more accurate values. Some studies indicate that a preferred time frame may start as early as 6 weeks to 3 months.[5,16] These time frames could either be for initial testing or retesting.

It is suggested that future studies utilize multiple and repetitive functional tests such as strength, the one-legged hop test, climbing a full flight of stairs, and squatting for up greater amount of time and repetitions, to allow a more functional and comprehensive balance evaluation on the participants. One thing this study did not assess is strength. Incorporating strength testing using an isokinetic machine (i.e. Cybex) is may be beneficial. The use of an isokinetic machine could provide a greater reliability on

assessments including different types of contractions (isometric, eccentric, isokinetic, etc.); it can isolate specific joints, and has a rate of standardization. This is suggested because of the impact that strength has on balance and function.[12,14,30,31]

Conclusion

This study indicates that further research must be completed to assess the effects an ACLR has on balance and weight bearing. This study used analytical statistics to show that there were significant differences when answering some of the research questions.

The results in this study showed significant differences in slower movement time and impact index in the involved leg in participants with a patellar versus hamstring graft. The WBS showed significantly less weight bearing at 60 and 90 degrees of knee flexion in the involved leg versus uninvolved leg in all participants and at 30 degrees in the involved versus the uninvolved leg in participants with a hamstring graft. There was also significantly less weight bearing in the WBS test at 0, 30, and 60 degrees in the involved versus uninvolved leg in participants with patellar graft. Finally, no significant differences were found in movement time with the SUO test and WBS at 0, 30, 60 and 90 degrees for participants with the involved leg less then or equal to 18 months post-op versus participants greater than 18 months post-op.

Due to significant differences found in this study, the overall results show that there are some knee deficits following an ACLR. Deficits were found in the involved leg versus the uninvolved leg, patellar graft versus hamstring graft in weight bearing, movement time and impact index in the WBS and SUO, respectively.

This study showed varied significance for significant differences throughout all test results. The need for further studies exists relative to ACLR's and time post-op. This may help provide a better understanding and increase the knowledge surrounding ACLR's and their effect on balance.

With the increase in incidence of ACL injuries requiring reconstruction, studies such as these are needed. Following the recommendations and limitations from this study may provide better results for future studies on the ACLR. Optimistically, this will lead to better decision making on rehabilitation for ACLR's and improve ability to solve increasingly complex problems resulting in efficient cost-effective care. Findings could possibly be used for guidelines on rehabilitation in patients with post ACLR's.

APPENDIX A

REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW

University of North Dakota Institutional Review Board

Date: 4/24/2003 **Project Number:** IRB-200304-237

Principal Investigator: Danks, Meridee; Braodway, Kim; Grise, Carrie; Yamamoto, Nicole; Yuen, Franz

Department: Physical Therapy

Project Title: Examination of Balance and Weightbearing in Post ACL Reconstruction Utilizing the Weight Bearing and Step Up/Over Tests on the NeuroCom Balance Master

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on April 28, 2003 and the following action was taken:

☒ Project approved. **Expedited Review** Category No. 4
Next scheduled review must be before April 27, 2004

☒ **Copies of the attached consent form with the IRB approval stamp dated** April 28, 2003 **must be used in obtaining consent for this study.**

☐ Project approved. **Exempt Review** Category No. _____
This approval is valid until _____ as long as approved procedures are followed.
No periodic review scheduled unless so stated in the Remarks Section.

☐ **Copies of the attached consent form with the IRB approval stamp dated** _____ **must be used in obtaining consent for this study.**

☐ Minor modifications required. The required corrections/additions must be submitted to ORPD for review and approval. **This study may NOT be started UNTIL final IRB approval has been received.**
(See Remarks Section for further information.)

☐ Project approval **deferred. This study may not be started until final IRB approval has been received.**
(See Remarks Section for further information.)

REMARKS: **Any adverse occurrences in the course of the research project must be reported immediately to the IRB Chairperson or ORPD.**

Any changes in protocol or Consent Forms must receive IRB approval prior to being implemented. You must submit a memo with a copy of the Consent Form and a revised Human Subjects Review Form, with the appropriate signatures, to the Office of Research and Program Development for review and approval.

PLEASE NOTE: **Requested revisions for student proposals MUST include adviser's signature. All revisions MUST be highlighted.**

☑ Education Requirements Completed. (Project cannot be started until IRB education requirements are met.)

cc: Chair, Physical Therapy

Kathy Swank 4/28/03
Signature of Designated IRB Member Date
UND's Institutional Review Board

the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance atement or a completed 310 Form may be required. Contact ORPD to obtain the required documents.

(Revised 10/2002)

University of North Dakota Human Subjects Review Form

Please Note: The policies and procedures of the University of North Dakota apply to all activities involving the use of Human Subjects performed by faculty, staff and students conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedure governing the use of human subjects. When preparing your Human Subjects Review Form, use the attached "IRB Checklist".

Please provide the information requested below:

Principal Investigator: **Meridee Danks, Kim Broadway, Carrie Grise, Nicky Yamamoto, Franz Yuen**

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School/College: UNDSMHS Department: Physical Therapy

Student Adviser (if applicable): Meridee Danks

Telephone: (701) 777-3861 Address: P.O. Box 9037

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School/College: UNDSMHS Department: Physical Therapy

Project Title: Examination of Balance and Weightbearing in Post ACL Reconstruction Utilizing the Weight Bearing and Step Up/Over Tests on the NeuroCom Balance Master

Proposed Project Dates: Beginning Date: 4/14/03 Completion Date: 12/03

Funding agencies supporting this research:

(A copy of the funding proposal for each agency identified above MUST be attached to this proposal when submitted.)

___ YES or X NO Does the Principal Investigator or any researcher associated with this project have a financial interest in the results of this project? If yes, please submit, on a separate piece of paper, an additional explanation of the financial interest (other than receipt of a grant)

If your project has been or will be submitted to another Institutional Review Board(s), please list those boards below along with the status of each proposal.

_____ Date submitted: _____ Status: ___ Approved ___ Pending

_____ Date submitted: _____ Status: ___ Approved ___ Pending

Type of Project: Please check "Yes" or "No" for each of the following.

X YES or ___ NO New Project

___ YES or X NO Continuation/Renewal

___ YES or X NO Protocol Change for previously approved project (resubmit "Human Subjects Review Proposal" with changes bolded or highlighted and signed)

___ YES or X NO Does your project include Genetic Research? If yes, refer to Chapter 3 of the Researcher's Handbook for additional guidelines regarding your topic.

___ YES or X NO Does your project include Internet Research? If yes, refer to Chapter 3 of the Researcher's Handbook for additional guidelines regarding your topic.

___ YES or X NO Dissertation/Thesis

X YES or ___ NO Student Research Project

___ ___

___ YES or _X_ NO Will subjects or data be provided by Altru Health Systems?If yes, submit two copies of the proposal. A copy of the proposal will be provided to Altru.

___ YES or _X_ NO Will research subjects be recruited at another organization (e.g., hospitals, schools, YMCA) or will assistance with the data collection be obtained from another organization If yes, please list all institutions:_____

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands their involvement in that study, and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and, if possible, should be printed on letterhead.

Subject Classification: This study will involve subjects who are in the following special populations: Check all that apply.

____ Minors (< 18 years)	_X_ UND Students
____ Prisoners	____ Pregnant Women/Fetuses

____ Persons with impaired ability to understand their involvement and/or consequences of participation in this research

_X_ Other Volunteers from the local community

For information about protections for each of the special populations please refer to the protected populations section on the Office of Research and Program Development website.

This study will involve: Check all that apply.

_____ Deception	_____ Stem Cells
_____ Radiation	_____ Discarded Tissue
_____ New Drugs (IND)	_____ Fetal Tissue
_____ Non-approved Use of Drug(s)	_____ Human Blood or Fluids
_____ Recombinant DNA	_____ Other
_X_ None of the above will be involved in this study	_____

I. Project Overview

Balance is an essential component in carrying out all activities of daily living. The maintenance of balance is a complex process which involves the interplay between the central nervous system and musculoskeletal system. Many factors contribute to an individual's ability to safely maintain balance. Some of these are intrinsic deficits such as neurological, vestibular, or orthopedic pathologies such as a person's integrity of ligaments in the knee joint. Ligamentous integrity, and its effect on balance, in all populations (youth, middle-ages, and athletes), has been a topic of interest to researchers who have looked at ways of improving stability and functional activities. The purpose of this study is to identify any significant changes in balance/weight-bearing in individuals who have undergone surgical reconstruction of the ACL compared to healthy individuals with no knee pathologies.

II. Protocol Description

1. Subject Selection.

Subjects will consists of 30-45 volunteers from the local community as well as the UND student population which will be recruited by the researchers by word of mouth to local therapists/orthopedic doctors and by the use of fliers (copy of flier attached). Each subject will be at least 20 years of age and will have had an ACL reconstruction between 3 and 12 months ago. Subjects must have not had any PCL involvement and no current back, hip, knee, or ankle pathologies. Subjects must not have any neurological or vestibular disorders and must not be taking any medications that may affect balance. Subjects must not currently be using any assistive device. A questionnaire will be administered before participation and will be used to determine health information that may influence the subject's balance and ability to participate in the training program. Informed consent for this study will be obtained via a signed consent form (attached) before any testing or training procedures are performed. Due to the high number of subjects used, the potential for validity will increase.

2. Description of Methodology.

Informed consent will be obtained through the attached consent form. Each subject will be required to sign the form if they agree with the terms that are presented. Upon agreement they will be included into the study and given a copy of their consent form for future reference.

Research will be conducted at the University of North Dakota School of Medicine and Health Sciences in the Physical Therapy Department. Study will consist of one session lasting approximately 30-45 minutes.

Prior to performing the tests, each subject will be asked to complete a health questionnaire and a functional assessment questionnaire (attached). Following this, range of motion measurements of knee flexion and extension will be taken with the subject supine on a plinth and will then perform testing using the NeuroCom ® Balance Master system.

The NeuroCom® Balance Master system is a clinically acceptable and safe machine commonly used in physical therapy to assess balance. The NeuroCom® Balance Master system operates on two 9-inch by 60-inch forceplates that determine the amount of force being exerted by each foot. The total force information is transferred to the computer system where calculations are performed. The computer screen is equipped with a cursor to provide visual feedback on the location of the subjects center of gravity. The computerized measurements and feedback systems are what make the system unique and beneficial to both the subject and researcher. Intra-reliability for testing using the NeuroCom ® Balance Master will be established prior to the start of the study through an instrumentation class which each member of the research team is currently enrolled in. The research team includes 4 second-year Physical Therapy students supervised by Meridee Danks. Validity of the NeuroCom® Balance Master has been established through its ability to generate computerized printouts of objective, quantifiable data. Published literature supports the scientific efficacy and clinical use of the NeuroCom® Balance Master and acknowledges it as reliable and valid tools for assessing balance. During this session the subject will familiarize him or herself with the NeuroCom® Balance Master machine and how it works with a practice trial to compensate for the high learning curve. Actual data will be taken from the second(actual) trial. Standardized testing procedures will be followed by the researchers for the following tests:

1) Weight Bearing/Squat (WBS) (This test is an indicator of weight distribution. Normal individuals maintain body weight within 7% of equal on the two legs over full range of squatting positions.)
   This testing procedures tests the percentage of weight borne by each leg for one second while the subject is standing with knees fully extended, at 30 °, 60°, and 90° of knee flexion. This test has been proven to have high reliability for normal adults and elderly
2) Step Up/Over Analysis (This test is an indicator of left/right leg differences, vertical force control, limb loading and unloading, and execution time.)
   This test requires the subject to step up onto a 8 inch curb with one foot, then stepping down with the other foot. This is a simulation of functional activities such as climbing stairs, stepping up on curbs, and other obstacles and is a critical element of gait in daily life. Step Up/Over test has been proven to have moderate to high reliability for normal adults and elderly and both tests have sensitivity to ACL injuries.

During the testing procedures subjects will be asked to wear loose comfortable clothes, preferably shorts, as we will need access to the knee and will be barefoot during all balance testing.

Statistical analysis consisting of descriptive and analytical statistics will be used to compile the data. This will be done using an alpha level of .05 in determining significance of the results. Data gathered for each tests subject will be analyzed using a related samples t-test.

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

3. Risk Identification.

The risks associated with this study are minimal, but those that exist will be controlled. The physical risks included possible loss of balance during the assessment on the NeuroCom ® Balance Master. The risk of falling will be minimized by having at least one member of the research team spotting subjects during all testing procedures. In addition, verbal instructions demonstrations, and a practice session will be given to subjects prior to the balance assessment.

Participants dignity, self-respect, and privacy will be protected by the research team by 1) testing all subjects in a private, controlled environment, 2) giving subjects complete instructions regarding their role in the research project, 3) scheduling individual testing sessions to promote privacy, 4) informing the subjects that all information pertaining to their history and performance will be disclosed only with a number and that no names will be used, and 5) informing the subjects that this is a voluntary exercise and they may withdraw at any time from the testing without fear of retribution or prejudice.

The data collected will be linked to the consent forms by coded numbers. This link will only be available to the researchers of this study.

4. Subject Protection.

The results of the study will remain confidential and the data collected will be identified by a number known only to the researchers. All consent forms, questionnaires, and data reports will be kept in separate locked confidential files located in the Physical Therapy Department of the UND School of Medicine and Health Sciences for a minimum of three years following completion of this study. After this period of time the results and all forms will be destroyed. During this time only the researchers of this study will have access to this information. In the event that this research activity results in a physical injury, medical treatment will be as available as it is to a member of the general public in similar circumstances. The University of North Dakota and the researchers are not responsible for any such injury or treatment. Payment for any such treatment must be provided by you or by your third party payer, if any. Please see attached consent form.

III. Benefits of the Study

This study has the potential for several benefits to both individual participants and society. Through assessment using the NeuroCom ® Balance Master, each participant will learn about their functional capabilities due to their ACL Reconstruction. Data results will help provide physical therapists and other health professionals with evidence-based research to assist in determining when normal function returns. This could in turn help prevent or decrease the risk of injuries occurring secondary to loss of balance created by instability of the knee joint due to the integrity of the ACL. Finally, results could be utilized by informing PT's on directing treatment towards balance training and weight bearing activities.

IV. Consent Form

A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects. Refer to the ORPD website for further information regarding consent form regulations.

Please note: Regulations require that all consent forms, and all pages of the consent forms, be kept for a minimum of 3 years after the completion of the study, even if subject does not continue participation. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. It is recommended that the consent form be written in the third person (please see the examples on the ORPD website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp. The consent form must include the following elements:

a) An introduction of the principal investigator

b) An explanation of the purposes of the research

c) The expected duration of subject participation

d) A brief summary of the project procedures

e) A description of the benefits to the subject/others anticipated from this study

f) A paragraph describing any reasonably foreseeable risks or discomforts to the subject

g) Disclosure of any alternative procedures/treatments that are advantageous to the subject

h) An explanation of compensation/medical treatment available if injury occurs.

i) A description of how confidentiality of subjects and data will be maintained. Indicate that the data and consent forms will be stored separately for at least three years following the completion of the study. Indicate where, in general, the data and consent documents will be stored and who has access. Indicate how the data will be disposed of. Be sure to list any mandatory reporting requirements that may require breaking confidentiality.

j) The names, telephone numbers and addresses of two individuals to contact for information (generally the student and student adviser). This information should be included in the following statement: "If you have questions about the research, please call (insert Principal Investigator's name) at (insert phone number of Principal Investigator) or (insert Adviser's name) at (insert Adviser's phone number). If you have any other questions or concerns, please call the Office of Research and Program Development at 777-4279."

k) If applicable: an explanation of who to contact in the event of a research-related injury to the subject.

l) If applicable: an explanation of financial interest must be included.

m) Regarding Participation in the study:

1) An indication that participation is voluntary and that no penalties or loss of benefits will result from refusal to participate.

2) An indication that the subject may discontinue participation at any time without penalty, with an explanation of how they can discontinue participation.

3) An explanation of circumstances which may result in the termination of a subject's participation in the study.

4) A description of any anticipated costs to the subject.

5) A statement indicating whether the subject will be informed of the findings of the study.

6) A statement indicating that the subject will receive a copy of the consent form.

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

Signatures:

(Principal Investigator) Date:

(Student Adviser) Date: 4-22-03

Requirements for submitting proposals:

Additional information can be found at the Office of Research and Program Development website at **www.und.nodak.edu/dept/orpd**

Original Proposals and all attachments should be submitted to: Office of Research and Program Development (ORPD), P.O. Box 7134, Grand Forks, ND 58202-7134, or drop off at Room 105, Twamley Hall.

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require Full Board review, you will need to provide additional copies. Further information can be found on the ORPD website regarding required copies and IRB review categories, or you may call the ORPD office.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 7 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 7 copies of the company's protocol must be provided.

Please Note: Student Researchers must complete the attached "Student Consent to Release of Educational Record".

To: UND IRB

From: Meridee Danks, Kim Broadway, Carrie Grise, Nicole Yamamoto, and Franz Yuen

We are writing in regards to a change in our original approved IRB. The approval date was April 28, 2003. Our research project number is IRB-200304-237 and is titled: Examination of Balance and Weightbearing in Post ACL Reconstruction Utilizing the Weight Bearing and Step Up/Over Tests on the NeuroCom Balance Master. We have found that the population of subjects will be greatly increased if we changed the time frame required to participate in the study from 3 to 12 months out to at least three months out. Attached are copies of the revised IRB and consent form, both of which have highlighted changes. Also is a copy of a revised consent form that can be stamped if the revisions are approved. Thank you for your time.

Thank You,

Meridee Danks
Carrie Grise
Kim Broadway

APPENDIX B

Consent Form

Title: Examination of Balance and Weightbearing in Post ACL Reconstruction Utilizing the Weight Bearing and Step Up/Over Tests on the NeuroCom Balance Master.

You are invited to participate in a study conducted by students of the University of North Dakota Physical Therapy Program, Kim Broadway, Carrie Grise, Nicky Yamamoto, and Franz Yuen, in collaboration with faculty Meridee Danks. The purpose of this study is to determine the effects on balance and weight-bearing following ACL reconstruction. Subjects for the study must have had an ACL reconstruction at least three months ago and be at least 18 years of age. All volunteers in this age group will be eligible for the study unless there is a safety or health concern excluding you from the study. You will be asked to complete a brief health questionnaire prior to participation in the study to ensure your eligibility in this study. You will also be asked to fill out a functional assessment questionnaire to inform us of your progress. You will be asked to wear loose, comfortable clothes preferably shorts as we will need access to the knee and you will be barefoot during all balance testing.

Your participation in the study will involve taking a measurement of the motion in your knee and an assessment on the NeuroCom® Balance Master. Testing will consist of one session lasting approximately 30-45 minutes. The NeuroCom® Balance Master is a machine commonly used to test balance in a physical therapy setting. Testing will include squatting at 0 degrees, 30 degrees, 60 degrees, and 90 degrees and three trials stepping up and over an 8 inch curb. A practice trial will be given before actual testing.

Although the process of balance assessment involves some risk of falling or injury, researchers feel the risk is minimal. Risk will be minimized through proper instructions and supervision with a spotter throughout testing procedures. If you choose to participate in this study you will benefit from involvement in a research setting and the knowledge that you will be helping to improve the field of physical therapy. You may also benefit from gaining knowledge of your own functional abilities.

The results of this study will remain confidential and your data will be identified by a number known only to the researchers. This consent form and your results will be kept in separate locked cabinets in a locked office in the Physical Therapy Department at the University of North Dakota for three years following completion of the study. After this period of time, your results will be destroyed. Your decision whether or not to participate will not change your future relations with the University of North Dakota or the Physical Therapy Department. If you decide to participate, you are free to discontinue participation at any time without it being help against you. If it is determined that you have a health condition that may affect your balance you may be excluded from the study.

The researchers will be available to answer any questions you may have concerning this study. Questions may be answered by calling Meridee Danks at (701) 777-3861, or Kim

Broadway at 780-2858, Carrie Grise at 746-6703, or emailing us at kspies@medicine.nodak.edu. You may also contact the UND Office of Research and Program Development at (701) 777-4278. A copy of this consent form will be provided to you for future reference.

In the event that this research activity results in a physical injury, medical treatment will be as available as it is to a member of the general public in similar circumstances. The University of North Dakota and the researchers are not held responsible for any such injury or treatment. Payment for any such treatment must be provided by you or your third party payer, if any.

All of my questions have been answered and I am encouraged to ask any questions that I may have concerning this study in the future. I have read all of the above and my signature below indicates my willingness to participate in this study explained to me by Kim Broadway, Carrie Grise, Nicky Yamamoto, and/or Franz Yuen.

_____

Participant's Signature Date

APPENDIX C

Subject #_____
Date:_____

Health Background Questionnaire

1. Do you have any current or past medical diagnosis or injury other than your ACL that affects your balance? (i.e. recent fractures, sprains, surgery of the hip, knee, or ankle, back problems, inner ear infections, vestibular disorders) If so, please describe.

2. Are you currently taking any medications? Please list all over the counter and prescription medications so we can determine if these may affect you balance.

3. Do you currently have any symptoms of dizziness or lightheadedness?

4. Have you been diagnosed with any psychological conditions (i.e. depression)?

5. Have you had two or more unexplained falls within the last 6 months?

6. Do you have normal vision with or without glasses/contact lenses?

7. What was the date of your ACL reconstruction surgery?

8. What was repaired during your surgery?

9. What type of graft was used (i.e. hamstring, patellar, allograft)?

10. Have you had any previous knee injuries right and/or left?

11. Are you at least 20 years of age?

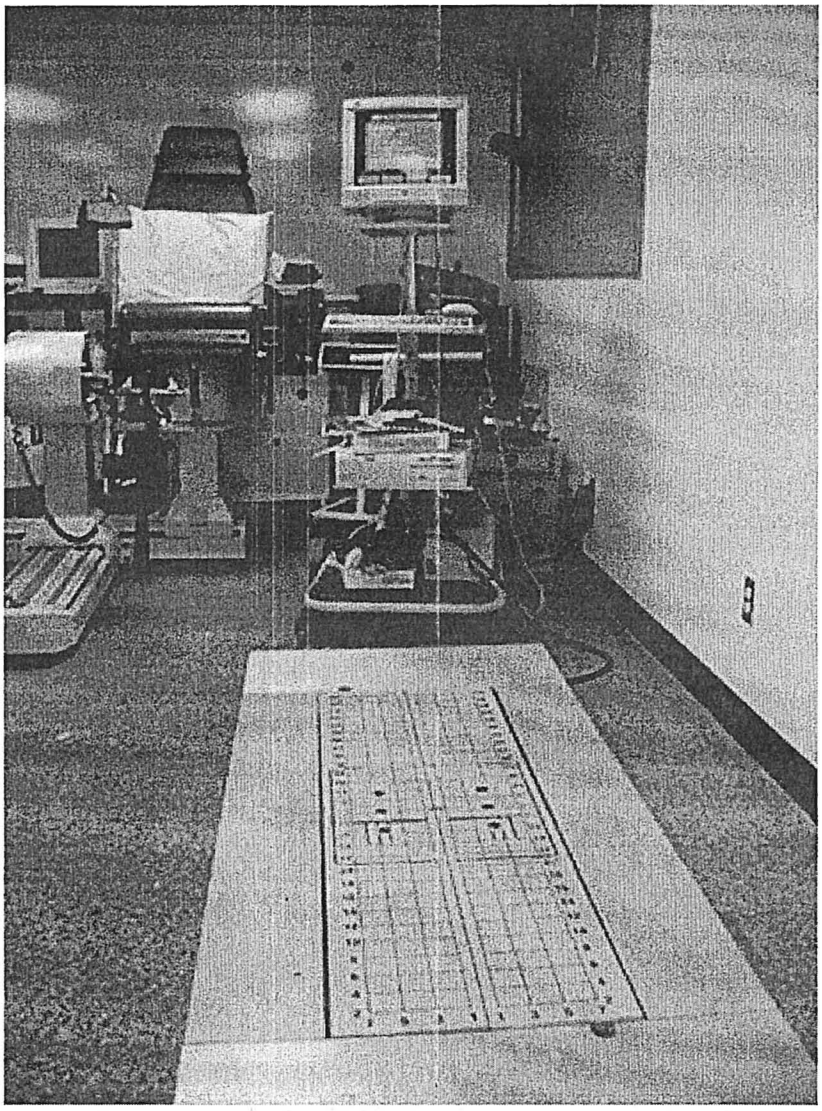
12. What type of rehab program were you enrolled in (include type, frequency, completed exercises as instructed)?

13. Have you returned to previous activity/exercise level (explain if full, partial, or minimal)?

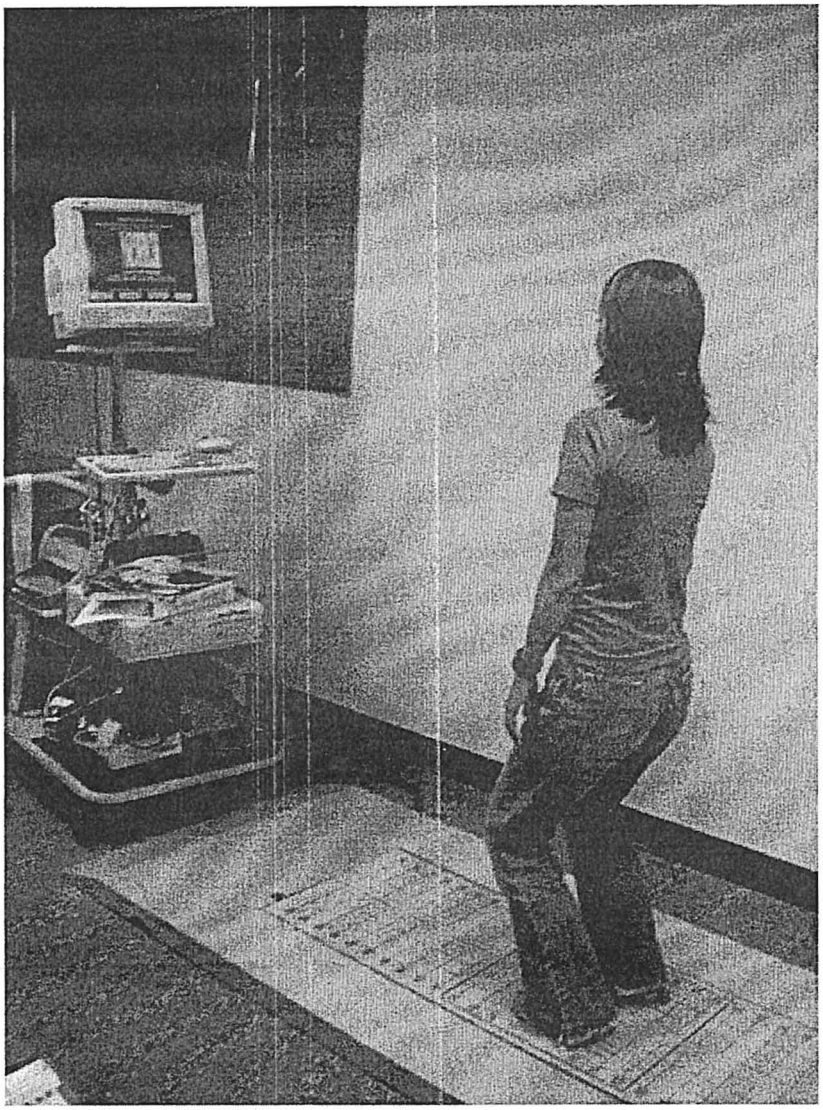
This part is to be filled out by the researchers.

Knee Range of Motion: **(in the supine position)**	**Right**	**Left**
Flexion		
Extension		

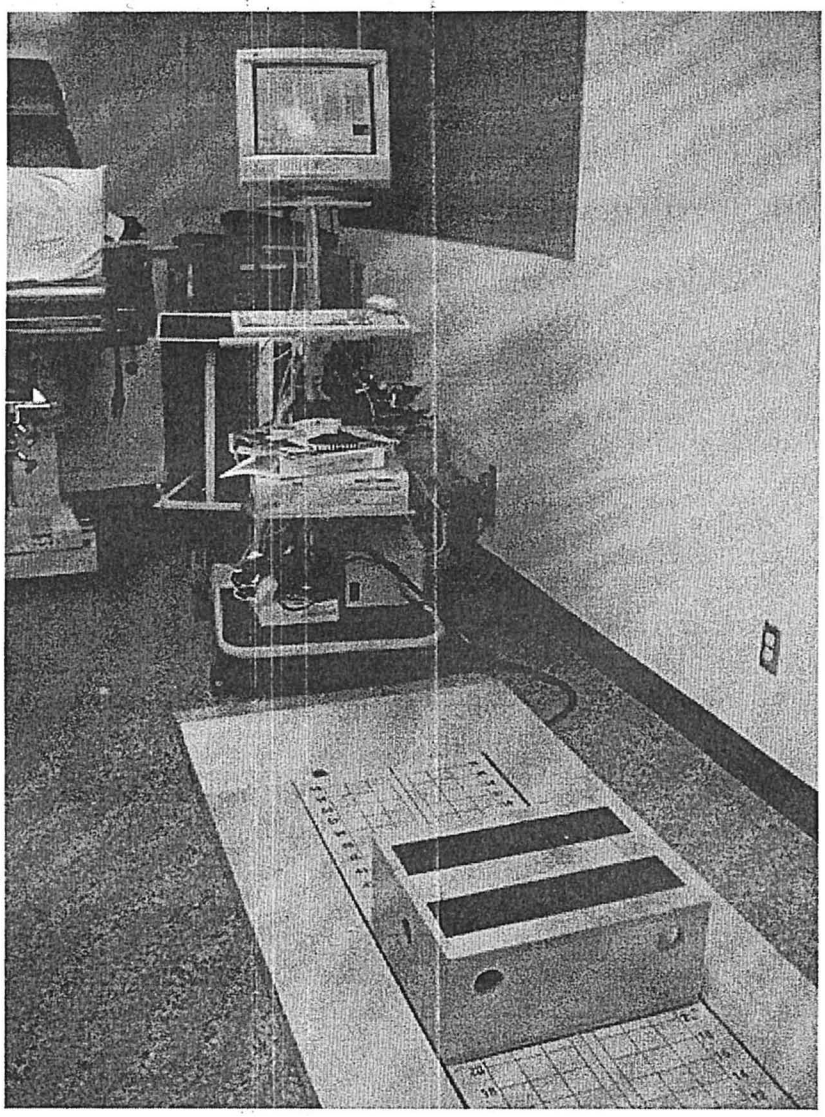
APPENDIX D



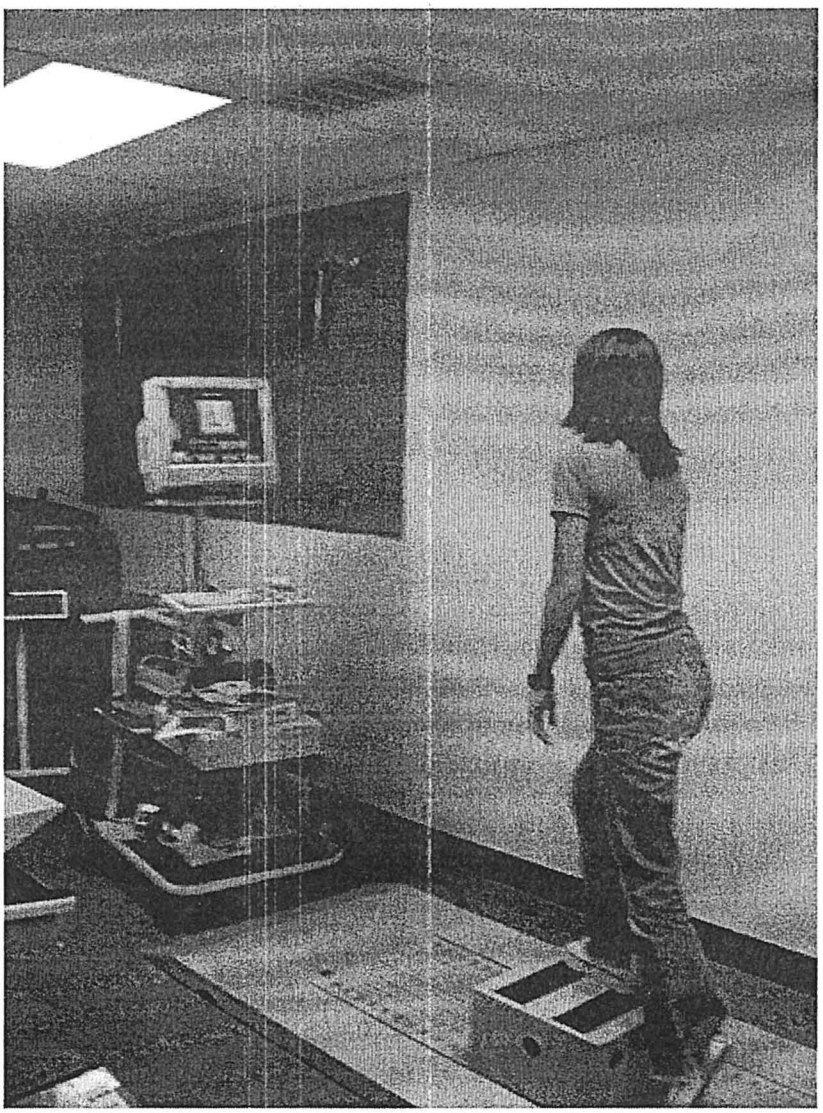
NeuroCom Balance Master
Computer and Forceplates



Beginning Position for Weight Bearing Squat Test
of the NeuroCom Balance Master



Set Up for Step Up/Over Test
on the NeuroCom Balance Master



Beginning Position for Step Up/Over Test
on the NeuroCom Balance Master

APPENDIX E

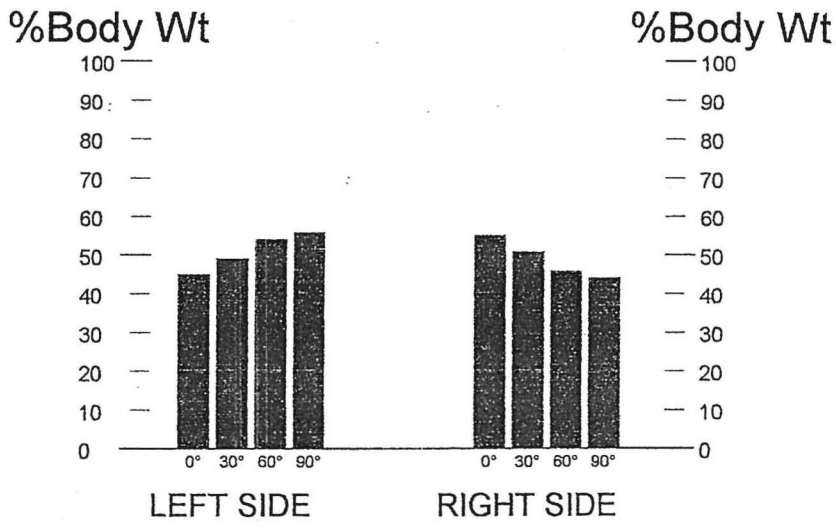
Name: 1, 0
ID: ATID00147
Date of Birth: -
Height: 5'6"

Comments:

Diagnosis: Not Specified
Operator: Not Specified
Referral Source: Not Specified

File: FD147.DRX
Date: 7/16/2003
Time: 10:28:50

Weight Bearing/Squat



Percentage Weight Bearing

Angle	Left	Right
0°	45	55
30°	49	51
60°	54	46
90°	56	44

Data Range Note:
No Data Range.

Post Test Comment:

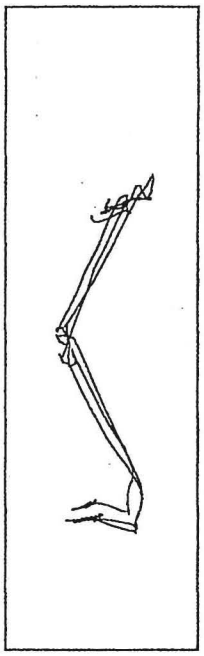
APPENDIX F

Name: 1, 0
ID: ATID00147
Date of Birth:
Height: 5'6"
Comments:

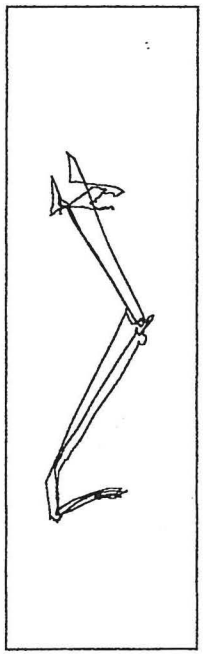
Diagnosis: Not Specified
Operator: Not,Specified
Referral Source: Not Specified

File: FD147.DRX
Date: 7/16/2003
Time: 10:31:55

Step Up/Over (8 inch curb)

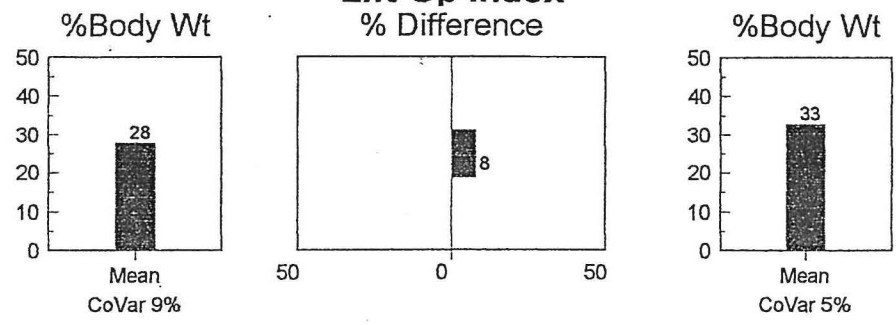


LEFT SIDE

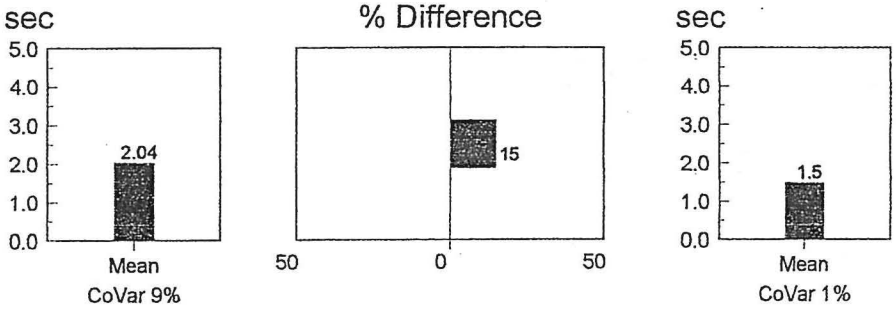


RIGHT SIDE

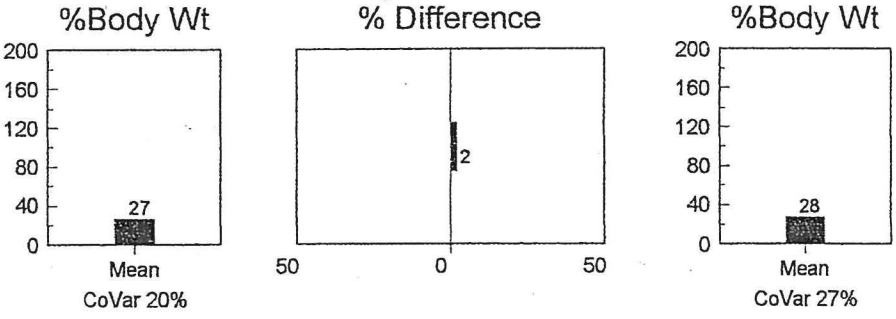
Lift-Up Index



Movement Time



Impact Index



Data Range Note:
No Data Range.

LEFT SIDE | LEFT/RIGHT DIFFERENCE | RIGHT SIDE

Post Test Comment:

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